K111661 (1/1)

AUG 19 2011

2 510(k) Summary of Safety and Effectiveness

Date Summary Prepared	June 9, 2011
Manufacturer/Distributor /Sponsor	Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA
510(k) Contact	Courtney Smith Manager, Regulatory Affairs Arthrex, Inc. 1370 Creekside Boulevard Naples, FL 34108-1945 USA Telephone: 239/643.5553, ext. 1720 Fax: 239/598.5508 Email: courtney.smith@arthrex.com
Trade Name	***Graft-Anchor***
Common Name	Screw, Fixation, Bone
Product Code - Classification Name	HWC – Screw, fixation, bone MBI – Fastener, fixation, nondegradable, soft tissue 21 CFR 888.3030: Single/multiple component metallic bone fixation appliances and accessories. 21 CFR 888.3040: Smooth or threaded metallic bone fixation fastener
Predicate Devices	*K063479*: Arthrex Mini PushLock
Device Description and Intended Use	The ***Arthrex Graft-Anchor*** is a one-piece titanium "push-in" anchor and comes pre-loaded on a driver. The ***Arthrex Graft-Anchor*** is intended to be used for suture or tissue fixation in the foot/ankle, knee, hand/wrist, elbow, and shoulder.
Substantial Equivalence Summary	The ***Arthrex Graft-Anchor*** is substantially equivalent to the ***Arthrex Mini PushLock*** predicate, in which the basic features, and intended uses are the same. Any differences between the *Graft-Anchor* and the predicate are considered minor and do not raise questions concerning safety and effectiveness. The mechanical testing demonstrates that the pull-out strength of the proposed devices meets or exceeds the pull-out strength of the predicate device. Based on the indication for use, technological characteristics, and the comparison to the predicate device, Arthrex, Inc. has determined that the ***Arthrex Graft-Anchor*** is substantially equivalent to currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Arthrex, Inc.
% Ms. Courtney Smith
Manager Regulatory Affairs
1370 Creekside Boulevard
Naples, Florida 34108-1945

AUG 19 2011

Re: K111661
Trade/Device Name: Arthrex Graft-Anchors
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, HWC
Dated: August 3, 2011
Received: August 4, 2011

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1 Indications for Use Form

Indications for Use

510(k) Number: *K111661*

Device Name: *Arthrex Graft-Anchor*

Indications For Use:

Indications for Use:

The Arthrex Graft-Anchor is intended to be used for suture or tissue fixation in the foot/ankle, knee, hand/wrist, elbow, and shoulder. Specific indications are listed below:

Elbow:	Biceps Tendon Reattachment, Ulnar or Radial Collateral Ligament Reconstruction
Shoulder:	Rotator Cuff Repair, Bankart Repair, SLAP Lesion Repair, Biceps Tenodesis, Acromio-Clavicular Separation Repair, Deltoid Repair, Capsular Shift or Capsulolabral Reconstruction
Hand/Wrist:	Scapholunate Ligament Reconstruction, Repair/Reconstruction of collateral ligaments, Repair of Flexor and Extensor Tendons at the PIP, DIP and MCP joints for all digits, digital tendon transfers, Carpal Ligament Reconstruction and Carpometacarpal joint arthroplasty (basal thumb joint arthroplasty)
Foot/Ankle:	Lateral Stabilization, Medial Stabilization, Achilles Tendon Repair, Metatarsal Ligament Repair, Hallux Valgus reconstruction, digital tendon transfers, Mid-foot reconstruction
Knee:	Medial Collateral Ligament Repair, Lateral Collateral Ligament Repair, Patellar Tendon Repair, Posterior Oblique Ligament Repair, Iliotibial Band Tenodesis

Prescription Use _X_ AND/OR Over-The-Counter Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. McKeon

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111661